scope of their disclosure—a legitimate exercise since it is for the inventors to decide what bounds of protection they will seek. Moreover, Applicants respectfully submit that In re Johnson, 194 USPQ 187 (C.C.P.A. 1977) provides legal precedent allowing the addition of this proviso. See also MPEP § 2163.05(II).

II. Information Disclosure Statements

Applicants respectfully repeat their request that the Examiner's consideration of Information Disclosure Statements already submitted in this case be made of record. See Information Disclosure Statement Under 37 C.F.R. § 1.97(b) filed May 26, 1998, and First Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(b) filed December 4, 1998, and Amendment and Response Under 37 C.F.R. § 1.111 filed July 17, 2000, at page 9. Applicants respectfully request the Examiner to consider the submitted documents, and to provide Applicants with initialed copies of the 1449 forms to indicate her consideration of the submitted documents. If the Examiner needs a copy of any of the submitted documents, or of the IDS papers, the undersigned will provide them upon request.

III. Claim Rejections Under 35 U.S.C. § 102

In the Office Action dated December 5, 2000, claims 41-43, 50, and 52 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Yoshimasa et al. (J. SCCJ 22(3), 165-170 (1988) (CAPlus abstract).) The Office Action alleges that "Yoshimasa et al. teach piroctone olamine that is 1-hydroxy-4-methyl-6-(2,4,4-trmethylpentyl)-2(1H)pyridone as an effective agent for inhibiting P. ovale that is responsible for seborrheic dermatitis, dandruff and itching." The Office Action continues

LAW OFFICES
NEGAN, HENDERSON,
ARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
HINGTON, DC 20005
202-408-4000

that "[a]ll critical components [of Applicants' claims] are anticipated by this. Thus the claimed subject matter [is] not patentably distinct over the prior art." Office Action at p. 2. Applicants respectfully traverse, at least because they disagree with the rejection and with the characterization of Yoshimasa et al.

Claims 43, 50, and 52 have been canceled, thus, the rejection is moot as to these claims. However, the subject matter of claim 43 has been incorporated into claim 38, and claims 41-42 remain. Therefore, Applicants address these allegations as follows.

Yoshimasa et al., according to the CAPlus abstract provided by the Examiner, teaches that "P. ovale, a yeast, is known as a resident flora on the scalp and closely related to seborrheic dermatitis. It has been reported that an increase of P. ovale causes dandruff and itching from adolescence to adulthood." The assimilation of various components of human sebum lipid by the yeast was tested, as were many substances, for possible inhibition of P. ovale. The abstract concludes:

> The inhibition agents of P. ovale were (1) herbal exts. (Swertia ext.), (2) perfume materials (cinnamic alc., cis-jasmone, geraniol, terpeneol, and undecylenic ldyhyde [sic]), (3) preservatives (benzoic acid and Na dehydroacetate), and (4) antidandruff agents (hinokitiol, Zn pyrithione, and piroctone olamine). Hinokitiol was the most effective inhibitor of P. ovale.

Applicants point out that no method of <u>treating</u> seborrheic dermatitis is taught by Yoshimasa et al. While Yoshimasa et al. states that P. ovale is "closely related to seborrheic dermatitis," the link between inhibiting P. ovale and treating seborrheic dermatitis has not been established.

In contrast, claim 38 recites "[a] method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising the step of administering to the

LAW OFFICES
NEGAN, HENDERSON,
ARABOW, GARRETT,
& DUNNER, L.L.P.
300 I STREET, N. W.
SHINGTON, DC 20005
202-408-4000

patient an amount effective for the treatment of seborrheic dermatitis of a 1-hydroxy-2-pyridone of formula I . . . ." See Claim 38, set forth above.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 (citation omitted). Yoshimasa et al. cannot be said to disclose a method for treating seborrheic dermatitis, and certainly it cannot be said that Yoshimasa et al. discloses an effective amount of a compound of formula I for that treatment. Thus, Yoshimasa et al. does not anticipate claim 38. Claims 41 and 42, and all other claims pending in this application, depend directly or indirectly from claim 38. Therefore, Yoshimasa et al. does not anticipate those claims either.

For the foregoing reasons, Applicant respectfully requests that this rejection be withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 103

Claims 38-40, 44-49, and 51 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Lohaus et al. (US 4,797,409) or Dittmar et al. (US 4,185,106) in view of Yoshimasa et al. The Office Action at page 3 characterizes the teachings of Lohaus and Dittmar, and concludes that

> [i]t would have been obvious to one of ordinary skill in the art to apply this patented or claimed formula to treat seborrheic dermatitis when either Lohaus or Dittmar's teaching is taken in view of Yoshimasa et al. because [Yoshimasa et al.] teach piroctone olamine . . . which is one of derivatives claimed, as [an] effective agent for inhibiting P. ovale that is responsible for seborrheic dermatitis, dandruff, and itching.

The Office Action asserts that one of ordinary skill in the art allegedly would have been motivated to apply the disclosed compositions to seborrheic dermatitis because of the

LAW OFFICES
NEGAN, HENDERSON,
ARABOW, GARRETT,
& DUNNER, L.L.P.
300 I STREET, N. W.
SHINGTON, DC 20005
202-408-4000

several advantages of these compounds. See id. Applicants respectfully traverse this rejection, and the reasoning therefor. Moreover, Applicants do not necessarily agree with the characterizations of any of the cited documents.

Lohaus et al. does not teach antiseborrheic activity, nor activity against any yeast associated with seborrheic dermatitis. Moreover, Dittmar et al. teaches away from the present invention. In spite of disclosing 1-hydroxy-2-pyridones, Dittmar et al. reveals that disclosed compositions may "contain further additives [such as] . . . anti-seborrheic agents . . . ." Dittmar et al. at col. 6, lines 11 and 24. Thus, one of ordinary skill in the art reading Dittmar et al. would be taught away from using disclosed 1-hydroxy-2-pyridones as an effective agent for treating seborrheic dermatitis.

The Office Action attempts to augment and overcome these teachings with Yoshimasa et al. As described above, Yoshimasa et al. describes a number of substances which inhibit the growth of P. ovale, and concludes that hinokitiol was the most effective inhibitor of P. ovale. Thus, to one of ordinary skill in the art, Yoshimasa et al. suggests that piroctone olamine, an "antidandruff agent," is as effective at inhibiting P. ovale as certain perfumes, herbal extracts, and preservatives. Considering Dittmar's teaching away, and Yoshimasa's equivocal teaching, one of ordinary skill in the art would be likely to select hinokitiol, or perhaps some nice-smelling cis-jasmone, in any attempt to find a treatment for seborrheic dermatitis.

For these reasons, Applicants assert that it would be, at best, merely obvious to try Yoshimasa's piroctone olamine for the treatment of seborrheic dermatitis, given the teachings of the cited documents. "Obvious to try" is insufficient to render a claim unpatentable. See, for example, In re Dow Chem. Co. v. American Cyanamid Co., 837

LAW OFFICES
NEGAN, HENDERSON,
ARABOW, GARRETT,
& DUNNER, L.L.P.
300 I STREET, N. W.
SHINGTON, DC 20005
202-408-4000

F.2d 469, 5 USPQ 2d 1529 (Fed. Cir. 1988); and In re Tomlinson, 363 F.2d 928, 150 USPQ 623 (C.C.P.A. 1966).

V. Applicants' Alleged Admissions

The Office Action seems to find an admission by the Applicants in the Amendment and Response Under 37 C.F.R. § 1.111 filed July 17, 2000:

> As [Applicants] acknowledged in the response filed July [17], 2000, [Applicants are] aware [that] piroctone olamine is effective against P. ovale that is responsible for seborrheic dermatitis and dandruff, where Yoshimasa et al. also stated that hinokitiol has better efficacy against the said yeast. It is very clear that the efficacy of the claimed compound against P. ovale has been taught in this reference. Therefore, the claimed subject matter is not patentably distinct and [remains] rejected.

Office Action at 4. Applicants respectfully traverse this assertion of an alleged admission. In their Amendment filed July 17, 2000, at page 11, Applicants cited their specification for the concept that "seborrheic dermatitis is thought to be caused by yeast fungi of the strain Pityrosporum." This can hardly be stated to be an admission that "Pityrosporum ovale is responsible for seborrheic dermatitis." Moreover, Applicants do not agree that the efficacy of piroctone olamine against Pityrosporum ovale is "very clearly" taught by Yoshimasa et al. To say this would be to take the position that the efficacy of, for example, cis-jasmone is also "very clearly" taught.

In sum, Applicants disagree that they have made any admissions regarding the teachings of Yoshimasa et al., or of any documents. Applicants ask that the words of these documents be taken as they should be - as they would be by one of ordinary skill in the art at the time the invention was made, to the extent that the documents would be applicable as prior art against the pending claims.

LAW OFFICES
NEGAN, HENDERSON,
ARABOW, GARRETT,
& DUNNER, L.L.P.
300 I STREET, N. W.
SHINGTON, DC 20005
202-408-4000

VI. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Applicants submit herewith a Petition for Extension of Time (One Month) and the fee therefor. Please grant any further extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 4, 2001

By: Jeremy M. Stipkala
Jeremy M. Stipkala
Reg. No. 44,359

Enclosure: Appendix

LAW OFFICES
NEGAN, HENDERSON,
ARABOW, GARRETT,
& DUNNER, L.L.P.
300 I STREET, N. W.
SHINGTON, DC 20005
202-408-4000

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having one or two rings which are optionally substituted by one, two, or three radicals, which may be identical or different, which are halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, or trifluoromethoxy, wherein the 1-hydroxy-2-pyridone of formula I or the pharmaceutically acceptable salt thereof is administered to the patient in a pharmaceutical composition, the

LAW OFFICES
FINEGAN, HENDERSON, FARABOW, GARRETT, & DUNNER, L.L.P.
300 I STREET, N. W.
SHINGTON, DC 20005
202-408-4000

pharmaceutical composition further comprising at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants, and mixtures thereof;

with the proviso that the 1-hydroxy-2-pyridone of formula I is not 6-(4-(4-chlorophenoxy)-phenoxymethyl)-1-hydroxy-4-methyl-2-pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone, or a pharmaceutically acceptable salt of either of the foregoing.

39. (Amended) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim ~~[38]~~ 49 in which the 1-hydroxy-2-pyridone of formula I comprises Ar as a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether.

40. (Amended) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim ~~[38]~~ 49 in which the 1-hydroxy-2-pyridone of formula I comprises a cyclohexyl radical in the R^4 position.

41. (Amended) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim ~~[38]~~ 49 in which the 1-hydroxy-2-pyridone of formula I comprises an octyl radical of the formula $-CH_2-CH(CH_3)-CH_2-C(CH_3)_3$ in the R^4 position.

LAW OFFICES
NEGAN, HENDERSON,
ARABOW, GARRETT,
& DUNNER, L.L.P.
100 I STREET, N. W.
SHINGTON, DC 20005
202-408-4000

42. (Amended) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim ~~[38]~~ 49 in which the 1-hydroxy-2-

pyridone of formula I is [~~1-hydroxy-4-methyl-6-(4-(4-chlorophenoxy)phenoxymethyl)-2(1H)pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone, or~~] 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)pyridone, or a pharmaceutically acceptable salt thereof [~~of any of the foregoing~~].

48. (Amended) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim [~~43~~] 49 in which the pharmaceutical composition further comprises a mixture of at least two surfactants, which are identical or different, and are anionic, cationic, nonionic, and amphoteric surfactants.

49. (Amended) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis as claimed in claim [~~43~~] 38 in which the pharmaceutical composition has a pH from about 4.5 to about 6.5.

LAW OFFICES
NEGAN, HENDERSON,
ARABOW, GARRETT,
& DUNNER, L.L.P.
300 I STREET, N. W.
SHINGTON, DC 20005
202-408-4000